

**ASSEMBLY BILL**

**No. 1442**

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**Introduced by Assembly Member Wieckowski**

January 4, 2012

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An act to amend Sections 117935, 117945, 117960, 118000, and 118165 of, and to add Sections 117637, 117748, and 118032 to, the Health and Safety Code, relating to pharmaceutical waste.

LEGISLATIVE COUNSEL'S DIGEST

AB 1442, as introduced, Wieckowski. Pharmaceutical waste.

The existing Medical Waste Management Act, administered by the State Department of Public Health, regulates the management and handling of medical waste, as defined. Existing law requires that all medical waste be hauled by either a registered hazardous waste hauler or by a person with an approved limited-quantity exemption granted pursuant to specified provisions of law. Violation of these provisions of law is a crime.

This bill would define pharmaceutical waste for purposes of the Medical Waste Management Act, and would authorize a medical waste generator or parent organization that employs health care professionals who generate pharmaceuticals to apply to the enforcement agency for a pharmaceutical waste hauling exemption if the generator, health care professional, or parent organization retains specified documentation and meets specified requirements. The bill would authorize pharmaceutical waste to be transported by the generator or health care professional who generated the pharmaceutical waste, a staff member of the generator or health care professional, or common carrier, as defined, pursuant to these provisions. By expanding the definition of a crime, this bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes.

State-mandated local program: yes.

*The people of the State of California do enact as follows:*

1 SECTION 1. Section 117637 is added to the Health and Safety  
2 Code, to read:

3 117637. “Common carrier” means either of the following:

4 (a) A person or company that has a United States Department  
5 of Transportation number issued by the Federal Motor Carrier  
6 Safety Administration and is registered with the Federal Motor  
7 Carrier Safety Administration as an interstate motor carrier and  
8 for-hire property carrier.

9 (b) A person or company that has a motor carrier of property  
10 permit issued by the Department of Motor Vehicles pursuant to  
11 the Motor Carriers of Property Permit Act (Division 14.85  
12 commencing with Section 34600) of the Vehicle Code) and a  
13 carrier identification number issued by the Department of the  
14 California Highway Patrol pursuant to Section 34507.5 of the  
15 Vehicle Code.

16 SEC. 2. Section 117748 is added to the Health and Safety Code,  
17 to read:

18 117748. (a) “Pharmaceutical waste” means any pharmaceutical,  
19 as defined in Section 117747, that for any reason may no longer  
20 be sold or dispensed for use as a drug.

21 (b) For purposes of this part, “pharmaceutical waste” does not  
22 include any pharmaceutical that still has potential value to the  
23 generator because it is being returned to a reverse distributor, as  
24 defined in Section 4040.5 of the Business and Professions Code,  
25 that is licensed both as a wholesaler of dangerous drugs by the  
26 California State Board of Pharmacy pursuant to Section 4160 of  
27 the Business and Professions Code and as a permitted transfer  
28 station pursuant to Section 117775, for possible manufacturer  
29 credit.

1 SEC. 3. Section 117935 of the Health and Safety Code is  
2 amended to read:

3 117935. Any small quantity generator required to register with  
4 the enforcement agency pursuant to Section 117930 shall file with  
5 the enforcement agency a medical waste management plan, on  
6 forms prescribed by the enforcement agency containing, but not  
7 limited to, all of the following:

8 (a) The name of the person.

9 (b) The business address of the person.

10 (c) The type of business.

11 (d) The types, and the estimated average monthly quantity, of  
12 medical waste generated.

13 (e) The type of treatment used onsite.

14 (f) The name and business address of the registered hazardous  
15 waste hauler used by the generator for backup treatment and  
16 disposal, for waste when the onsite treatment method is not  
17 appropriate due to the hazardous or radioactive characteristics of  
18 the waste, ~~or~~, the name of the registered hazardous waste hauler  
19 used by the generator to have untreated medical waste removed  
20 for treatment and disposal, *and, if applicable, the name of the*  
21 *common carrier used by the generator to transport pharmaceutical*  
22 *waste offsite for treatment and disposal pursuant to Section*  
23 *118032.*

24 (g) A statement indicating that the generator is hauling the  
25 medical waste generated in his or her business pursuant to Section  
26 118030 and the name and any business address of the treatment  
27 and disposal facilities to which the waste is being hauled, if  
28 applicable.

29 (h) The name and business address of the registered hazardous  
30 waste hauler service provided by the building management to  
31 which the building tenants may subscribe or are required by the  
32 building management to subscribe and the name and business  
33 address of the treatment and disposal facilities used, if applicable.

34 (i) A statement certifying that the information provided is  
35 complete and accurate.

36 SEC. 4. Section 117945 of the Health and Safety Code is  
37 amended to read:

38 117945. Small quantity generators who are not required to  
39 register pursuant to this chapter shall maintain on file in their office  
40 all of following:

1 (a) An information document stating how the generator contains,  
2 stores, treats, and disposes of any medical waste generated through  
3 any act or process of the generator.

4 (b) Records of any medical waste transported offsite for  
5 treatment and disposal, including the quantity of waste transported,  
6 the date transported, ~~and~~ the name of the registered hazardous  
7 waste hauler or individual hauling the waste pursuant to Section  
8 118030, *and, if applicable, the name of the common carrier*  
9 *transporting pharmaceutical waste pursuant to Section 118032.*

10 The small quantity generator shall maintain these records for not  
11 less than two years.

12 SEC. 5. Section 117960 of the Health and Safety Code is  
13 amended to read:

14 117960. Any large quantity generator required to register with  
15 the enforcement agency pursuant to Section 117950 shall file with  
16 the enforcement agency a medical waste management plan, on  
17 forms prescribed by the enforcement agency containing, but not  
18 limited to, all of the following:

19 (a) The name of the person.

20 (b) The business address of the person.

21 (c) The type of business.

22 (d) The types, and the estimated average monthly quantity, of  
23 medical waste generated.

24 (e) The type of treatment used onsite, if applicable. For  
25 generators with onsite medical waste treatment facilities, including  
26 incinerators or steam sterilizers or other treatment facilities as  
27 determined by the enforcement agency, the treatment capacity of  
28 the onsite treatment facility.

29 (f) The name and business address of the registered hazardous  
30 waste hauler used by the generator to have untreated medical waste  
31 removed for treatment, if applicable, *and, if applicable, the name*  
32 *and business address of the common carrier transporting*  
33 *pharmaceutical waste pursuant to Section 118032.*

34 (g) The name and business address of the registered hazardous  
35 waste hauler service provided by the building management to  
36 which the building tenants may subscribe or are required by the  
37 building management to subscribe, if applicable.

38 (h) The name and business address of the offsite medical waste  
39 treatment facility to which the medical waste is being hauled, if  
40 applicable.

1 (i) An emergency action plan complying with regulations  
2 adopted by the department.

3 (j) A statement certifying that the information provided is  
4 complete and accurate.

5 SEC. 6. Section 118000 of the Health and Safety Code is  
6 amended to read:

7 118000. (a) Except as otherwise exempted pursuant to Section  
8 118030 *or* 118032, all medical waste transported to an offsite  
9 medical waste treatment facility shall be transported in accordance  
10 with this chapter by a registered hazardous waste transporter issued  
11 a registration certificate pursuant to Chapter 6 (commencing with  
12 Section 118025) and Article 6.5 (commencing with Section  
13 25167.1) of Chapter 6.5 of Division 20. A hazardous waste  
14 transporter transporting medical waste shall have a copy of the  
15 transporter's valid hazardous waste transporter registration  
16 certificate in the transporter's possession while transporting  
17 medical waste. The transporter shall show the certificate, upon  
18 demand, to any enforcement agency personnel or authorized  
19 employee of the Department of the California Highway Patrol.

20 (b) Except for small quantity generators transporting medical  
21 waste pursuant to Section 118030 *or small quantity generators or*  
22 *common carriers transporting pharmaceutical waste pursuant to*  
23 *Section 118032*, medical waste shall be transported to a permitted  
24 offsite medical waste treatment facility or a permitted transfer  
25 station in leak-resistant and fully enclosed rigid secondary  
26 containers that are then loaded into an enclosed cargo body.

27 (c) A person shall not transport medical waste in the same  
28 vehicle with other waste unless the medical waste is separately  
29 contained in rigid containers or kept separate by barriers from  
30 other waste, or unless all of the waste is to be handled as medical  
31 waste in accordance with this part.

32 (d) Medical waste shall only be transported to a permitted  
33 medical waste treatment facility, or to a transfer station or another  
34 registered generator for the purpose of consolidation before  
35 treatment and disposal, pursuant to this part.

36 (e) Facilities for the transfer of medical waste shall be annually  
37 inspected and issued permits in accordance with the regulations  
38 adopted pursuant to this part.

39 (f) Any persons manually loading or unloading containers of  
40 medical waste shall be provided by their employer at the beginning

1 of each shift with, and shall be required to wear, clean and  
2 protective gloves and coveralls, changeable lab coats, or other  
3 protective clothing. The department may require, by regulation,  
4 other protective devices appropriate to the type of medical waste  
5 being handled.

6 SEC. 7. Section 118032 is added to the Health and Safety Code,  
7 to read:

8 118032. (a) A medical waste generator or parent organization  
9 that employs health care professionals who generate pharmaceutical  
10 waste may apply to the enforcement agency for a pharmaceutical  
11 waste hauling exemption if the generator, health care professional,  
12 or parent organization meets all of the following requirements:

13 (1) The generator or parent organization has on file one of the  
14 following:

15 (A) If the generator or parent organization is a small quantity  
16 generator required to register pursuant to Chapter 4 (commencing  
17 with Section 117915), a medical waste management plan prepared  
18 pursuant to Section 117935.

19 (B) If the generator or parent organization is a small quantity  
20 generator not required to register pursuant to Chapter 4  
21 (commencing with Section 117915), the information document  
22 maintained pursuant to subdivision (a) of Section 117945.

23 (C) If the generator or parent organization is a large quantity  
24 generator, a medical waste management plan prepared pursuant  
25 to Section 117960.

26 (2) The generator or health care professional who generated the  
27 pharmaceutical waste transports the pharmaceutical waste himself  
28 or herself, or directs a member of his or her staff to transport the  
29 pharmaceutical waste to a parent organization or another health  
30 care facility for the purpose of consolidation before treatment and  
31 disposal, or contracts with a common carrier to transport the  
32 pharmaceutical waste to a permitted medical waste treatment  
33 facility or transfer station.

34 (3) Except as provided in paragraph (4), the generator maintains  
35 a tracking document, as specified in Section 118040.

36 (4) (A) Notwithstanding paragraph (3), if a health care  
37 professional who generates pharmaceutical waste returns the  
38 pharmaceutical waste to the parent organization, a single-page  
39 form or multiple entry log may be substituted for the tracking

1 document, if the form or log contains all of the following  
2 information:

3 (i) The name of the person transporting the pharmaceutical  
4 waste.

5 (ii) The number of containers of pharmaceutical waste. This  
6 clause does not require any generator to maintain a separate  
7 medical waste container for every patient or to maintain records  
8 as to the specified source of the pharmaceutical waste in any  
9 container.

10 (iii) The date that the pharmaceutical waste was returned.

11 (B) This paragraph does not prohibit the use of a single  
12 document to verify the return of more than one container to a parent  
13 organization or another health care facility for the purpose of  
14 consolidation before treatment and disposal over a period of time,  
15 if the form or log is maintained in the files of the parent  
16 organization or another health care facility that receives the waste  
17 once the form or log is completed.

18 SEC. 8. Section 118165 of the Health and Safety Code is  
19 amended to read:

20 118165. On and after April 1, 1991, all persons operating a  
21 medical waste treatment facility shall maintain individual records  
22 for a period of three years and shall report or submit to the  
23 enforcement agency upon request, all of the following information:

24 (a) The type of treatment facility and its capacity.

25 (b) All treatment facility operating records.

26 (c) Copies of the tracking documents for all medical waste it  
27 receives for treatment from offsite generators ~~or from~~, hazardous  
28 waste haulers, *or, pursuant to Section 118032, common carriers.*

29 SEC. 9. No reimbursement is required by this act pursuant to  
30 Section 6 of Article XIII B of the California Constitution because  
31 the only costs that may be incurred by a local agency or school  
32 district will be incurred because this act creates a new crime or  
33 infraction, eliminates a crime or infraction, or changes the penalty  
34 for a crime or infraction, within the meaning of Section 17556 of  
35 the Government Code, or changes the definition of a crime within  
36 the meaning of Section 6 of Article XIII B of the California  
37 Constitution.